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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,240

10/21/2005

Jan Henrik Ardenkjaer-Larsen

PS0269

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36335 7590 05/01/2009

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EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,240	Applicant(s) ARDENKJAER-LARSEN ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 2/10/2009, in reply to the Office Action mailed 8/14/2008, is acknowledged and has been entered. Claims 1, 2, 4-7, 10 and 11 have been amended. Claims 1-16 are pending, of which claims 12-16 have been withdrawn as being drawn to a non-elected invention. Claims 1-11 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Any rejection not reiterated herein has been WITHDRAWN.

Applicant's arguments filed 2/10/2009 have been fully considered but they are not persuasive, for reasons set forth hereinbelow.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons set forth in the previous Office Action.

Applicant argues that the specification refers to suitable substrate compounds which may be used in the claimed method to be hydrogenated with para-hydrogen enriched hydrogen as those found in WO 99/24080. Applicant asserts that WO 99/24080 entered national phase from the PCT in the US and resulted in granted US patent number 6,574,495. Applicant has amended the specification referring for the first time to WO 99/24080 by including the term "now issued as United States Patent No. 6,574,495 on June 03, 2003."

This is not found to be persuasive. There is no description of the claimed hydrogenatable, unsaturated substrate compound required to make and use the contrast agent broadly claimed. There is no description provided regarding what type of specific chemical moieties are used to represent the substrate that would render such a compound to be useful as a contrast agent. There is very little predictability in the art concerning any undefined species which may represent a substrate compound and which chemical moiety would represent a substrate out of an almost unlimited number of chemical species which may be possible. The specification does not provide any guidance to the specific identity or physical/chemical structure of the variables which represent a substrate, and because the structures of these elements are undefined, it is unclear how Applicant envisaged suitable elements to satisfy the functional requirements of the substrate. Regarding the specification as amended, it is respectfully noted that a WO document is a publication, and a WO document does not "issue into a US patent," as cited by Applicant. Accordingly, the claims are objected to as introducing new matter. Furthermore, an incorporation by reference must express a

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clear intent to incorporate by reference by using the words “incorporate” and “reference” (see 37 CFR 1.57(b)). In the instant case, no such statement exists, and thus there is no clear intent to incorporate by reference the subject matter that identifies a hydrogenatable, unsaturated substrate compound, and no adequate description of such a compound has been provided. A description of the identity of a suitable substrate compound is considered to be essential material to the method which is claimed.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelsson *et al.* (WO 00/071166, whereby US 6,872,380 is relied upon as equivalent), for reasons set forth in the previous Office Action.

Applicant argues on pages 8-9 of the Response that Axelsson is discussed in the present application at page 2, line 22-page 3, line 7 and page 15, lines 28-29. Applicant asserts that it is stated that the magnetic field cycling method described in Axelsson is an adiabatic remagnetization, while claims 1-11 clearly state that in the magnetic field cycling method according to the present invention, the increase in magnetic field is carried out such that non-adiabatic re-magnetization of contrast agent is obtained. Applicant further argues that Axelsson does not disclose, teach or suggest that further increase of polarization can be achieved with the use of a magnetic field cycling method

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wherein an increase of magnetic field is carried out such that non-adiabatic re-magnetization is obtained.

This is not found to be persuasive. As set forth in the previous Office Action, Axelsson specifically teaches decrease in magnetization and increase in magnetization times which are identical to those claimed.

The instant specification at page 15, lines 26+, recites "the following difference to the prior art methods, described for example in WO 00/71166 should be noted: in the prior art methods the field is suddenly reduced and followed by a *comparably slow adiabatic remagnetization prevailing for up to some tens of seconds*, the field increase preferably follows an exponential curve. In the method according to the present invention a controlled reduction of the field is *followed by a comparably rapid increase of the field, giving a non-adiabatic (diabatic) remagnetization*."

Applicant's specification describes the correlation of adiabatic/non-adiabatic processes as depending on the rate of magnetization. Axelsson meets the requirements of the rates of decrease and increase of magnetic fields as defined in the dependent claims, thus it is interpreted, absent evidence to the contrary, that the method of Axelsson also inherently meets the limitation of non-adiabatic remagnetization, whether or not such remagnetization times are preferred. **Axelsson is not limited to longer time periods for remagnetization.** For example, Axelsson teaches that remagnetization is 10-10000 ms, preferably 100-1000 ms (column 3, lines 40-45), however, patents are relevant as prior art for all they contain. See MPEP 2123 (1). "The use of patents as references is not limited to what the patentees describe as

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their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005). Therefore, the disclosure of Axelsson that remagnetization occurs at e.g. 10 ms, would be directly readable upon the instant claims. See for example claim 11 of Axelsson which teaches decrease in field strength is ≤ 1 ms, and increase back to ambient strength may be 10 ms. Such a timeframe is directly readable upon the instantly claimed decrease/increase times defined in instant claims 3-9.

Regarding the argument that Axelsson does not recite further polarization increase, the "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Power Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function, or new property, which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), and MPEP § 2112. Since Axelsson discloses method steps which are readable upon the instantly claimed steps, Axelsson meets the claims.

Double Patenting

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/526,238, for reasons set forth in the previous Office Action.

Applicant argues on page 9 of the Response that both sets of claims are drawn to increasing the polarization of a MR contrast agent produced by hydrogenation of a substrate compound with para-hydrogen enriched hydrogen by magnetic field treatment, but that the way this magnetic field treatment is carried out during the exposing step is technically different, and due to this technical difference the claims are not obvious variants of one another.

This is not found to be persuasive. The decrease and subsequent increase in magnetic field strength of the instant claims is overlapping in scope with at least two pulses which differ in magnetic field strength of the claims of the '238 Application.

Specification

The amendment filed 2/10/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: after the term WO 99/24080: "now issued as United States Patent No. 6,574,495 on June 03,2003." However, it is respectfully noted that a WO document is a publication, and a WO

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document itself does not "issue into a US patent," as cited by Applicant. Accordingly, the specification is objected to as introducing new matter into the disclosure.

Conclusion

No claims are allowed at this time.

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS